Promoting Self-Management in Stroke Survivors Using Health-IT

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ABSTRACT

Purpose

To test usability, feasibility and efficacy of mobile health technology (mHealth) in facilitating hypertension self-management in stroke survivors.

Scope

Self-measured blood pressure monitoring can be useful in improving hypertension control especially when combined with other support. We examine mHealth facilitated self-monitoring in stroke survivors.

Methods

Design was a randomized clinical trial. Participants were stroke survivors, aged between 40-80 years, recruited from University of Minnesota stroke service and acute rehabilitation unit. Intervention was mHealth facilitated blood pressure self-monitoring with protocol based medication adjustment. Control subjects received usual care. Most participants were followed for 90 days though some needed extended monitoring.

Results

A total of 49 (25 intervention, 24 control) participants completed the trial. Intervention participants transmitted blood pressure data for 89% of the days under monitoring. Usability Survey results indicate that stroke survivors were highly satisfied with the mHealth system and, that it helped them be more involved in their health care. At study completion, 92% of intervention participants and 54% of control participants had their blood pressures controlled into guideline specified ranges. We conclude that mHealth facilitated hypertension management appears to be feasible and efficacious in stroke survivors.

Keywords

mHealth, hypertension, self-monitoring

PURPOSE

This is a pilot study to test usability, feasibility and efficacy of health-IT, specifically mobile health technology (mHealth), in facilitating vascular risk factor self-management in stroke survivors. The specific risk factor targeted in this study is hypertension (HTN). The goal of this study is to inform a larger health system based study on the clinical effectiveness of mHealth based interventions.

SCOPE

Stroke survivors are at a very high risk of recurrent stroke, heart attacks and heart failure due to the high prevalence of HTN, diabetes mellitus and elevated cholesterol in this population. Unfortunately, post-discharge stroke care in the community is fragmented and inconsistent. [1,2] There is sub-optimal management of vascular risk factors in the outpatient setting and medication non-compliance by stroke survivors. [3] A large population based study showed that 51% of stroke survivors had elevated blood pressure 1 year post-stroke with 19% having severe elevations (BP ≥ 160/95). [4] Two-thirds of stroke survivors have residual disabilities and are frequently dependent on elderly caregivers for transportation to clinic visits. Interventions to improve medication compliance and reduce caregiver burden can prevent hospital readmissions and ultimately decrease societal costs of medical care for stroke survivors.

The 2014 American Heart/Stroke Association Guidelines state that, *the treatment of hypertension is possibly the most important intervention for the prevention of stroke*. [5,6] Self-measured blood pressure monitoring (SMBP) can be useful in improving HTN control. A meta-analysis of SMBP was found to lower blood pressure (BP) compared to usual care without self-monitoring. [7] Additional support was found to further lower the BP. Consequently, SMBP is recommended by the AHA guidelines and JNC-7 as an adjunct to improve HTN control. [5,6,8,9] An AHA Statement on the Use of Mobile Devices for CVD prevention found that mHealth can facilitate SMBP and thereby improve HTN control. [8] The review also found that while mHealth showed efficacy in reducing BP in hypertensive patients, there were significant gaps in the evidence for clinical effectiveness. A key question was whether mHealth facilitated HTN management was generalizable to a larger population and broader consumer base including the elderly and disabled such as those with stroke? [8] Our pilot study addresses this evidence gap.

METHODS

The study was approved by the University of Minnesota institutional review board (IRB), (1212M25581).

Design

Study design was a randomized controlled trial (RCT) design with 2 parallel arms.

Intervention

The intervention arm was mHealth based HTN management. Intervention participants were instructed on the importance of HTN management after stroke. They were provided with a smart phone and a wireless BP monitor. They were trained on using the wireless equipment for SMBP and instructed to self-monitor their BP daily. Participants were instructed to measure their BP prior to breakfast, coffee or medications. The smart phone transmitted their daily BP automatically to a database. Study investigators reviewed BP weekly and adjusted anti-hypertensive medications typically bi-weekly. Study investigators used 7-day moving averages of daily BP to make decisions on medication adjustments. If a patient measured BP multiple times during the day, the earliest set of BP measurements for the day was used. We examined all the BP within a 20 minutes window starting with the first BP of the day, and, then used the last BP in that 20 minute window as the BP used for decision making. Patients were instructed on proper, standard techniques for BP measurement. Primary care providers (PCP) were involved in medication change decisions for the intervention arm. HTN was managed according to the AHA and JNC-7 guideline recommendations with PCP input.

Control

Control participants were given a digital BP monitor, education on the importance of HTN management after stroke and, instructed to follow up with their PCP.

Study duration

Participants were followed for 90 days. When HTN control could not be achieved in some of the intervention participants within 90 days, we went back to the IRB to obtain permission for extended monitoring as needed to achieve HTN control.

Participants

Participant recruitment took place on the inpatient acute stroke unit as well as on the acute rehabilitation unit. Included were acute stroke survivors aged 40-80 years, with a neurologist validated ischemic stroke or intra-parenchymal hemorrhage. Participants had to be able to communicate in English, able to use or learn to use the mHealth equipment, answer survey questions and, have a new diagnosis or history of HTN. Participants were excluded if they were unable to give consent or complete the required trial tasks. Initially, we did not exclude co-morbid conditions. But over the course of the trial, based on our experience with the complexity of managing HTN in patients on dialysis, we excluded participants with significant comorbid conditions.

Data

Outcomes of interest were primarily usability and feasibility of mHealth technology for HTN control in stroke survivors and the rates of HTN control into guideline based ranges. Usability was measured at the end of the study in intervention participants by using the Marshfield Usability Survey. Feasibility was measured by the number of days BP was transmitted by

intervention participants. HTN control was operationalized as the BP < guideline thresholds of < 140/90 mm Hg.

Analysis

We examined mHealth system usability by measures of centrality (mean, median) of the elements of the Marshfield Usability Scale. System feasibility was analyzed as the percentage of days BP was transmitted compared to days BP monitoring was done. Percentages of subjects with HTN controlled into the guideline specified threshold was compared between the two groups. Since this was a pilot study, our analysis was an "as-treated" analysis.

RESULTS

A total of 56 participants were randomized with 34 in the intervention arm and 22 in the control arm. Of these, 6 intervention participants withdrew or were withdrawn by investigators. The reasons for withdrawal are shown in Table 1. Two intervention participants crossed over into the control arm. Of the total 50 patients in the study (excluding 6 withdrawals), 25 (of 26) intervention patients have completed the study and 24 control patients have completed the study. One intervention patient is yet to complete the study and his data is incomplete. As-treated analysis was completed on 25 intervention and 24 control participants. In the intervention arm, 23% of the participants were of the female sex. In the control arm, 33% were female. Mean age of participants in the intervention arm was 64 years, (SD 9, range 43-82 years). In the control arm, mean age of participants was 69 years, (SD 10, age range 47-85 years).

Table1. Reasons for participant withdrawal from study

Reason for withdrawal	N	Withdrawn by	Comment
Was on dialysis; BP was too complex to manage due to changes in dialysate	1	Investigator	This was an early patient; Patients on dialysis and other complex medical conditions excluded going forward
Died soon after randomization before medication adjustment was started	1	Investigator	Death was likely sudden cardiac death and not related to study.
Had large vessel (carotid) occlusion and BP management was very gentle consequently	1	Investigator	BP was controlled and was a success as far as trial outcome was concerned. However, patient received extra attention due to medical complexity; going forward we excluded participants with carotid occlusion
Felt overwhelmed after stroke; withdrew after randomization but before starting the study	1	Participant	
Felt cuff was pinching her arm; withdrew after randomization but before starting the study	1	Participant	None of the other patients complained about the cuff

Tripped on furniture while walking in the dark and was hospitalized for many weeks with subdural	1	Investigator	Study criteria was that patient would be withdrawn from study if they were not able to transmit for more than 2 weeks

Feasibility of mHealth for HTN management

Mhealth intervention participants transmitted BP data for an average of 89% of days under monitoring and, 92% of subjects transmitted their BP for more than half the monitored days. Most participants had their HTN controlled within 90 days (19/26). Some participants needed more than 90 days for HTN control. We extended their monitoring period (with IRB approval) until HTN control was achieved (7/26). One patient in the extended monitoring group is still transmitting as he has not yet completed the study. Some survivors have continued daily BP measurement after the study ended stating that it has become a habit.

Table 2. MHealth was feasible for HTN management in stroke survivors

Total N = 26	Days Transmitted	Participants N (%)
90 day monitoring N = 19	80-90 70-79 60-69 50-59 < 50	12 (63) 3 (16) 1 (5) 1 (5) 2 (11)
Extended monitoring N=7	Transmitted daily until HTN controlled 103, 107, 113,115, 121 days Transmitted 91 of 101 monitored days	6 (86) 1 (14)
Patients transmitted BP readings on average 89% of days under monitoring. 92% of subjects transmitted their BP for more than half the monitored days.		

Usability of mHealth for HTN management in stroke suvivors

The Marshfield Usability Survey results indicate that stroke survivors were highly satisfied with the mHealth system, found it easy to use, that they would like to use it again and that it helped them be more involved in their health care (Table 3).

Table3. Results of the Marshfield Usability Survey: (1=Strongly Disagree; 2=Disagree; 3= Neither Agree nor Disagree; 4=Agree; 5=Strongly Agree). Results indicate very high usability. N = 25.

	Mean	Median
I thought the system was easy to use	4.6	5
Using the system did not take much time	4.5	4
I could always trust the system to work	4.1	4
My privacy was protected when I used the system	4.2	4
In general, I was satisfied with the system	4.5	5
I think most people could learn to use the system very quickly	4.5	5
I think I would like to use the system again	3.8	4
The system could help me better manage my health and medical	4	4
I could be more involved in my care by using the system	4	4

HTN Control into Guideline Specified Range

In the intervention arm, 56% (14/25) participants had their HTN controlled at enrollment and 92% (23/25) had their HTN controlled at study completion. In the control arm, 50% (12/24) had their HTN controlled at enrollment and 54% (13/24) had their HTN controlled at study completion (chi-square p = 0.02), Table 4. While some of the patients were controlled rapidly on 2 or 3 anti-hypertensive medications (Figure 1), some patients were quite difficult to control, needed 4 medications and prolonged monitoring (Figures 2).

Table 4. Efficacy of HTN control Intervention vs. Control

N	INTERVENTION	CONTROL
Randomized	34	22
Withdrawn (data not used)	6	0
Crossed Over From Intervention to Control	2	
As Treated Total	26	24
Still under Rx/Observation	1	0
Finished Observation	25	24
Study Start AND End Blood Pressure data reported on N	25	24
SBP < 140 mm Hg at enrollment (goal)	**14 (of 25; 56%)**	**12(of 24; 50%)**
SBP < 140 mm Hg at study end (goal)	**23 (of 25; 92%)**	**13(of 24; 54%)**
Reasons SBP was not at goal for Intervention patients		
• Resistance to Medication Changes	1	
• Technical difficulties in following procedures	1	
•		
Average SBP Study Start	139	140
Average SBP Study End	128	135
Average DBP Study Start	83	78
Average DBP Study End	77	76

Figure 1. Blood pressure trajectory of an intervention patient who was easy to manage. X-axis shows number of days of transmission. Patient was monitored for 90 days.

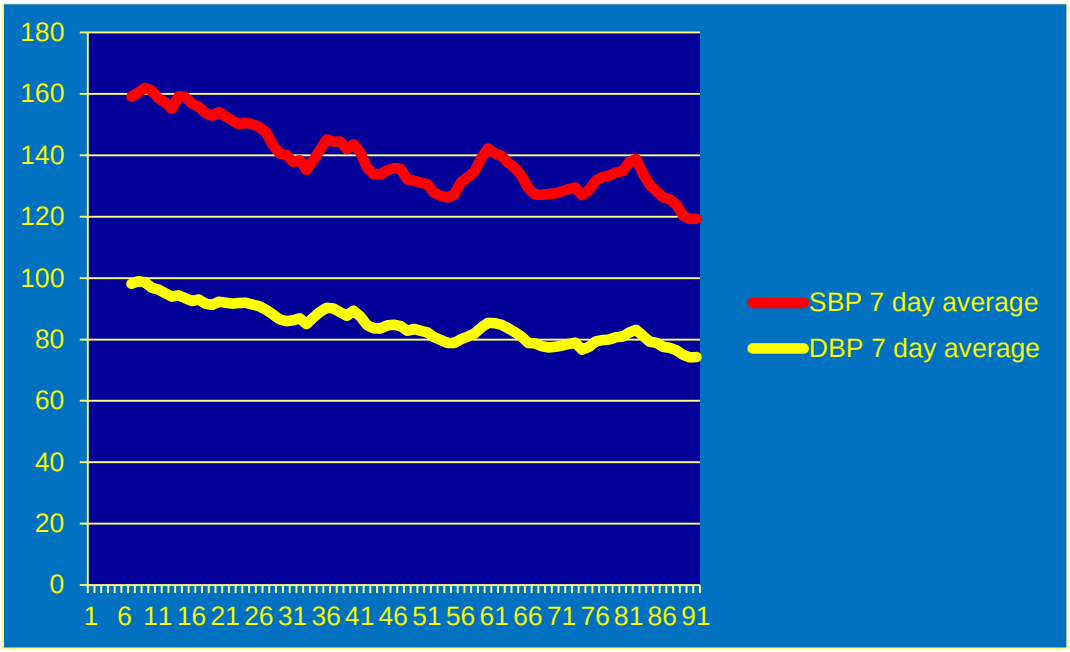
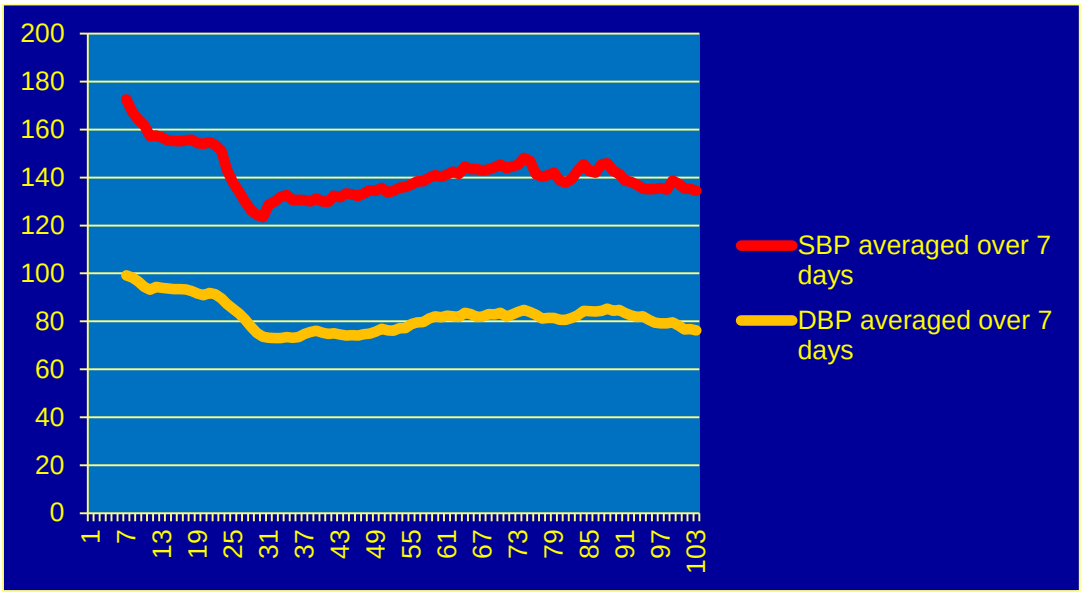


Figure 2. Blood pressure trajectory of an intervention patient who was more challenging to manage and needed extended monitoring and 4 anti-hypertensive agents.



DISCUSSION

mHealth technology for HTN management showed excellent usability and very high feasibility in stroke survivors. The rate of HTN control was significantly higher in the mHealth group compared to the usual care control group, based on an as-treated analysis. Since this is a pilot study with the goal of informing the design of a larger trial, we believe that an as-treated analysis is appropriate. Our results are significant. While our study shows efficacy of the intervention, there is need for demonstrating the clinical effectiveness of this technology on a larger scale within health systems, in populations including both stroke survivors as well as those at high risk of stroke and cardiovascular events. A sample size for this larger trial was estimated in the range of 300-400 participants.

Some of the lessons learned on this pilot study include clarification on appropriate exclusions. For example, medically complex patients and those with large vessel occlusions should be excluded from trial of protocol based HTN management. We also realized that the intervention was quite labor intensive since the investigators (Dr.Lakshminarayan, MD & Dr. Westberg, PharmD) discussed BP trajectories weekly and made medication adjustments biweekly. Translation of this study to a larger scale will require that providers be alerted only when BP exceeds pre-set parameters. These parameters would likely be guideline based thresholds.

Of note, we had excellent partnerships with primary care providers. They were quite happy to have their patients participate in the trial and appreciated the extra assistance in HTN management. Frequently, they reinforced the investigators messages regarding the need for medication compliance to the participants. One key reason aspect of our relationship with providers is that we did not stop any of the existing anti-hypertensive medications already added by the providers. Instead we made dose adjustments and added new medications as needed. We informed providers in advance of medication changes.

CONCLUSIONS

Our study shows excellent usability and feasibility of a mHealth system for HTN management after stroke. There was significant improvement in HTN control rates among participants who used the mHealth system compared to usual care controls. Our results call for a larger health system based trial in order to establish the long-term effectiveness of this approach for self-care of vascular risk factors and HTN management among high risk groups.

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